

REMARKS

Applicant acknowledges that this is a first Office Action following the filing of an RCE under 37 CFR 1.114 with claims 11-24 withdrawn from consideration. Claims 2-10 are currently pending.

Applicant has amended the Specification on Page 5, second paragraph, line 13 to change "DPK12-JH4" to - - DPK12-JK4- - and on Page 6, first paragraph, line 7 to change "DPH12-JK4" to - - DPK12-JK4- -. Support for this amendment to the Specification is found in the original specification, which cites BPK12 and JK4 in Fig. 4 and Example 7 as light chain variable regions.

In addition, Applicant has amended the Specification on page 6, by inserting the following between lines 30 and 31:

- The hybridoma cell line KKCTC1019BP corresponds to the pHmKR127HC vector and the hybridoma cell line KCTC10199BP corresponds to the PHuKR127KC vector. A scientific description of each microorganism was deposited pursuant to the Budapest Treaty and contains the following information:
 - 1. Depository:
Korea Research Institute of Bioscience and biotechnology (KRIBB),
#52 Oun-dong, Yusong-Ku, Taijon, 305-333, Republic of Korea.

2. Depositor: Hyo Jeong, HONG (Inventor):

Clover Apt. 117-2012, Dunsan-dong, Seo-Ku, Taejon 302-772,
Republic of Korea.

3. The date of Deposit: March 13, 2002 (both microorganisms).

4. Accession numbers: KCTC 10198BP, KCTXC 10199BP.

5. The date of viability test: January 17, 2005 (KCTC 10198BP)
January 21, 2005 (KCTS 10199BP). –

Lastly, the Specification has been amended to state that identification number <223> in the Sequence Listing should read “Variable region of humanized heavy chain HZVII”.

Further, Applicant is submitting herewith the sequences for JH4, JK4, DP7-JH4 and DPK12-JK4, respectively. The present specification already discloses the sequence list for DP7 and DPK12 as SEQ ID NO 31, 32(DP7) and SEQ ID NO 33, 34 (DPK12) respectively.

The attorney of record, Eugene Lieberstein, has executed a Declaration attesting to the Certificate of Deposit as provided by applicant which has been included herein along with a Viability Statement under 37 CFR 1.807.

Claim 2 has been amended to more clearly recite the invention of the present application. No new matter has been added.

Based on the amendments to the Specification, Claim 2, the submission of the Statement, the inclusion of a computer readable sequence and the Remarks below, Applicants believe that the present application is in condition for allowance and request that the Examiner forward it to issue.

Applicant acknowledges and thanks the Examiner for withdrawing the rejection of claim 3 under 35 USC 112, second paragraph, has been withdrawn.

Claims 6, 7, 9 and 10 were rejected under 35 USC 112, first paragraph for failing to comply with the enablement requirement . Applicants respectfully traverse this ground of rejection for the following reasons. Applicant has attached hereto a Certificate of Deposit for the hybridoma cell lines KKCTC1019BP and KCPC10199BP, respectively, which Applicant believes satisfies all of the requirements of the biological deposit requirements under the terms of the Budapest Treaty. The Certificate of Deposit includes a scientific description of each microorganism deposited, pursuant to the Budapest Treaty, and contains the following information:

1. Depository:

Korea Research Institute of Bioscience and biotechnology (KRIBB), #52 Oundong, Yusong-Ku, Taijon, 305-333, Republic of Korea.

2. Depositor: Hyo Jeong, HONG (Inventor):

Clover Apt. 117-2012, Dunsan-dong, Seo-Ku, Taejon 302-772, Republic of Korea.

3. The date of Deposit: March 13, 2002 (both microorganisms).
4. Accession numbers: KCTC 10198BP, KCTXC 10199BP.
5. The date of viability test: January 17, 2005 (KCTC 10198BP)
January 21, 2005 (KCTS 10199BP).

The attached Certificate of Deposit for KKCTC10198BP is an hybridoma cell corresponding to pHmKR127HC vector and the Certificate of Deposit for KCTC10199BP is a hybridoma cell corresponding to pHuKR127KC vector for producing the claimed constructs. Each vector comprises modified Dp7-JH4 and DPK12-JK4, respectively.

Accordingly, the rejection of claims 6, 7, 9 and 10 under 34 USC 112, first paragraph, should now be withdrawn.

Applicant has also amended the specification to include the sequences for JH4, JK4, DP7-JH4 and DPK12-JK4, respectively. The present specification already discloses the sequence list for DP7 and DPK12 as SEQ ID NO 31, 32(DP7) and SEQ ID NO 33, 34 (DPK12) respectively. Please note that the specification has been amended with "DPK12-JH4" and "DPH12-JK4" has been amended to DPK12-JK4 which was clearly a typographical error. Support for this amendment of the

Specification is found in the original specification, which cites BPK12 and JK4 in Fig. 4 and Example 7 as light chain variable regions.

The rejection of claim 2 under 35 USC 103(a) as being obvious of Leong et al (Cytokine, November 2001, Vol. 16 to p. 106-109), is respectfully traversed.

Amended Claim 2 reads as follows:

-- A process for preparing a humanized antibody consisting of the steps of: (a) first replacing each amino acid residue in the complementarily determining region (CDR) of murine monoclonal antibody heavy chain and light chain variable regions with alanine to produce transformants, selecting a transformant that has a lower affinity to the human antigen (K_D) than the original murine antibody, and determining the replaced amino acid residue of said transformant as a specificity determining residue (SDR) and (b) subsequently grafting said SDR to at least one of the corresponding amino acid residues into human antibody variable regions. --

Amended claim 2 now makes it explicit that step (a) must be carried out first followed by step (b) so that only SDR could be grafted onto human antibody. Such a limitation is not disclosed in Leong et al. Moreover, contrary to grafting CDR, as is taught in Leong, in the present invention only SDR grafting occurs, which is unexpected and results decreasing HAMA as is clearly evident from Example 9.

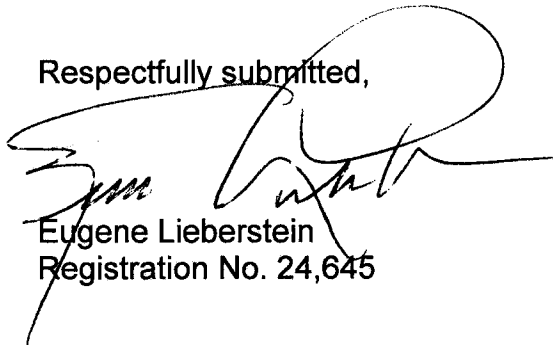
The method taught in Leong for grafting CDRs comprises performing alanine scanning mutagenesis of murine CDRs to determine the specificity determining regions (SDRs) and then grafting the alanine substituted CDR regions of the murine anti-IL-8 antibody onto a human IgG framework is contrary to the subject invention and will not minimize murine derived sequences. Step (b) in claim 1 is a step for grafting SDR which are amino acids selected from step (a). Accordingly, Leong does not follow this procedure nor is this obvious from Leong, since the subject invention is a process for grafting SDR and not for grafting CDR.

Accordingly, the rejection of claim 3 under 35 USC 103(a) should be withdrawn and the claim allowed.

The allowance of claims 4, 5 and 8 is acknowledged and appreciated.

Reconsideration and allowance of claims 2-10 is respectfully solicited.

Respectfully submitted,



Eugene Lieberstein
Registration No. 24,645

Dated: December 22, 2009

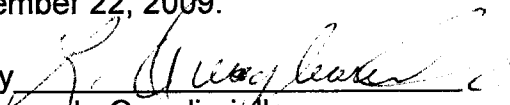
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CERTIFICATE OF TRANSMISSION

I hereby certify that this Amendment w/attachments is being sent to the U.S. Patent Office via EFS- Web to the Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on December 22, 2009.

By


L. Quagliariello